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Docket No.: CBR 3.0-016
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Alfred J. Moo-Young

Application No.: 09/154,283

Filed: September 16, 1998

Art Unit: 1617

For ANDROGEN AS A MALE CONTRACEPTIVE
: AND NON-CONTRACEPTIVE ANDROGEN
REPLACEMENT

Examiner: E. Webman

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RECEIVED

AUG 26 2003

DECLARATION OF DR. PEKKA LAHTENMAKI

TECH CENTER 1000, 2900

Dear Sir:

1. I, Pekka Lahteenmaki, am a citizen of Finland.
2. I am the Pekka Lahteenmaki who is listed as one of the authors on the Suvisaari et al. article, "Pharmacokinetics and pharmacodynamics of 7 α -methyl-19-nortestosterone after intramuscular administration in healthy men," Human Repod. (1997), 12(5), 967-973, a copy of which is attached hereto as Exhibit A.
3. I have also reviewed a "Declaration of Alfred J. Moo-Young under 37 C.F.R. § 1.131," which I understand was submitted to the U.S. Patent and Trademark Office in connection with pending Application No. 09/154,283 of Dr. Moo-Young. I have reviewed that declaration and it is my opinion that it is accurate. It correctly conveys the fact that it was Dr. Moo-Young's invention that androgen alone, and

without additional steroids, could be utilized for the purposes of contraception. Dr. Moo-Young has discovered that androgens such as 7 α -methyl-nortestosterone (MENT) can be utilized alone for such purposes. He also recognized that in order to be contraceptively effective, these particular androgens need to be used in at least certain required minimum dosage levels.

4. I also understand that Dr. Moo-Young presented Exhibit B attached to his declaration to demonstrate the collection of actual data in Helsinki, Finland, in which 15 men in groups of five received various dosages of MENT over a period of four weeks. That Exhibit B does mention that I, Dr. Lahteenmaki, presented the results from Helsinki to a meeting of the International Committee for Contraception Research at The World Population Council. However, I did not invent that which is the subject of pending Application Serial No. 09/154,283; namely, a method of male contraception comprising administering to a nonsterile male subject a predetermined amount or a non-5 α -reducible androgen sufficient to render the male subject reversably sterile for a predetermined period of time, and which provides the male subject with blood levels of LH and FSH of 2.5 IU/L or less, and testosterone of 10 mol/l or less and in which the androgen is substantially the only sterilizing agent administered to the male subject for the purposes of contraception. While I did organize and carry out the actual clinical studies which resulted in the results presented at the aforementioned meeting, I did so on the basis of Dr. Moo-Young's invention having been previously transmitted to me from Dr. Moo-Young. I therefore only carried out that which Dr. Moo-Young had invented, and I am therefore convinced that Dr. Moo-Young is the true inventor, and I am not.


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5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated:

1 August 2003



PEKKA LAHTENMAKI

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